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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,077	09/19/2000	Michael Climo	7732-020-27 DIV	5645

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EXAMINER
BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
1631	9

DATE MAILED: 07/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/665,077	Climo et al.
Examiner	**Art Unit**
Michael Borin	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 13, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *3-11 and 18-28* is/are pending in the application.

4a) Of the above, claim(s) *3-11 and 23-28* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *18-22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Claims

1. Claims 3-11, 18-28 are pending.

Response to restriction requirement and amendment filed 5/13/02 are acknowledged. Applicant elected, with traverse, Group II. Applicant argues that all pending claims "emphasize the parallel elements which run through all the pending claims", the parallel elements being lysostaphin and cell-wall active antibiotic. Restriction requirement does not dispute that; rather the restriction requirement states that the methods have different functions and the method of Group I is considered as an *in vivo* method, whereas method of Group II is viewed as *in vitro* method. Applicant argues the latter and introduces amendment "in a method of treatment" to claim 18. The amendment, however, is not considered to change the scope of the claim to *in vivo*, as it is not clear treatment of what (e.g.,in *in vivo or in vitro* conditions) is meant. The restriction requirement is still deemed proper and is therefore made FINAL.

Upon further consideration of the claims it was deemed necessary to merge claims 24-28, drawn to *in vivo* method of treatment of mammal, with Group I. Consequently, Group II, claims 18-22 is examined, claims 3-11,23-28 are withdrawn

from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 18 fails to particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claim addresses treatment of strains resistant to lysostaphin (lines 2-3). On the other hand the claims requires that not only strains resistant to lysostaphin are suppressed, but strains resistant to cell-wall active antibiotic and strains resistant to both lysostaphin and cell-wall active antibiotic are also suppressed (lines 7-9). Being resistant to lysostaphin does not automatically imply being resistant to other antibiotics. See, e.g., Chopra et al. and Pulverer et al references demonstrating lack of correlation between

lysostaphin and methicillin resistance. The specification, although providing particular examples, does not provide a standard for ascertaining the requisite strains, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

B. Further, claim 18 is confusing in that it uses two different ways of defining the dosage of antibiotics. From one side, these are common therapeutically effective dosages; from another side the doses are defined as satisfying triple requirement of suppressing I) lysostaphin-resistant strains, ii) strains resistant to cell-wall active antibiotic and iii) strains resistant to both lysostaphin and cell-wall active antibiotic. No correlation between dosage ranges defined in these two ways is present; consequently, one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

C. Claim 18, in the first definition of dosages, as described in the previous paragraph, recites the dosages "effective in therapeutical treating a staphylococcal infection in a mammal". Such definition is not clear as it does not define neither the type of staphylococcal infection, nor the kind of mammal.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 18-22 are rejected under 35 U.S.C. 102(b) as anticipated by Polak et al. (Diagn. Microbiol. Infect. Dis., 17, 265-270, 1993).

The reference teaches that *S.aueus* strain which was resistant to 100μg/ml of lysostaphin was suppressed by combination of said amount of lysostaphin with penicillin. See Table 3, line 5.

4. Claims 18-22 are rejected under 35 U.S.C. 103(a) as obvious over Shaffner (Yale J. Biol. Med. (1967), 39(4), 215-29) and Moreira (Antimicrobial Agents and Chemotherapy, (1997 Aug) 41 (8) 1788-93) or DeHart (Applied and Enviromental Microbiology, 1995, 4, 1475-1479).

The instant claims are drawn to method of enhancing the effectiveness of lysostaphin by suppressing lysostaphin-resistant strains combining lysostaphin and a cell-wall antibiotic taken at their regular concentrations.

Shaffner et al discovered in *in vitro* studies that in strains with reduced sensitivity to lysostaphin the sensitivity to penicillin increased. See pages 224-225. Later, Moreira demonstrated that the increased sensitivity to penicillin in lysostaphin resistant strains is due to increased production and activity of penicillin-binding proteins (PBPs) and suggested that such increased activity of PBPs allows penicillin to compete with lysostaphin in the lysostaphin-resistant strains. See abstract.

Further, DeHart reported similar observations with methicillin: strains having resistance to lysostaphin were more susceptible to methicillin than strains without lysostaphin resistance.

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to be motivated, in the event when lysostaphin-resistant strains are present in the culture, to augment effect of lysostaphin with penicillin, because

Shaffner, Moreira, and DeHart demonstrate that penicillin or methicillin will have enhanced bactericidal activity against lysostaphin-resistant strains and because inhibition of bacterial strains is a desirable effect.

Prior art made of record

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Blackburn (US 5,760,026) teaches that bactericidal activity of lysostaphin is potentiated by penicillin and other cell-wall antibiotics (col. 7).

Conclusion.

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

July 17, 2002

mlb